

REMARKS

Claims 1-6, 8-16, 19-25 and 28 were pending in the present application. By virtue of this response, claims 11-12 and 21-22 have been cancelled, without prejudice, and claims 1, 10 and 20 have been amended. Support for the amendment to claim 1 can be found at least at page 35, lines 4-14; and support for the amendment to claims 10 and 20 can be found at least at page 21, lines 14-26. Accordingly, claims 1-6, 8-10, 13-16, 19-20, 23-25 and 28 are currently under consideration. Amendment and cancellation of certain claims is not to be construed as a dedication to the public of any of the subject matter of the claims as previously presented. Applicant reserves the right to file any amended or cancelled subject matter in related applications.

Interview Summary

Applicant thanks Examiner Sullivan for extending the courtesy of a telephonic interview on November 30, 2005 regarding the outstanding rejections in the instant application. The following is a list of participants of the Telephonic Interview of November 30, 2005: USPTO participants: Daniel Sullivan; and Applicant's Morrison & Foerster, LLP representatives: Catherine Polizzi and Debra Glaister. The pending claims and references cited by the USPTO were discussed. Applicant thanks Examiner Sullivan for his helpful comments and suggestions, which are reflected herein.

Rejections under 35 U.S.C. § 112, Second paragraph

Claims 1-6, 8 and 9 are rejected under Section 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant traverses this rejection of claims. Applicant submits that the claims are in full compliance with Section 112, second paragraph. Without acquiescing to the rejection of claims and solely in an effort to expedite prosecution, Applicant has amended claim 1 to recite that the

composition is administered after an exposure to herpes simplex virus and within three days after the virus exposure in an amount sufficient to prevent a symptom of herpes simplex virus infection. thereby obviating this rejection. Applicant gratefully acknowledges Examiner Sullivan's agreement in the Telephonic Interview that the amendment to claim 1 should obviate the Section 112, second paragraph rejection of claims. Applicant respectfully requests withdrawal of this rejection of claims.

Rejections under 35 U.S.C. § 102(b)

I. Claims 1, 2, 8-11, 16, 19-21 and 28 stand rejected as allegedly being anticipated by Hutcherson et al. (1997) U.S. Patent No. 5,663,153 ("Hutcherson").

Applicant traverses this rejection of claims. For a claim to be anticipated by a reference, the reference must teach each and every element of the claim.

Claim 1 recites, in part, a method wherein the composition comprising a polynucleotide comprising an ISS is administered after an exposure to herpes simplex virus and within three days after the virus exposure in an amount sufficient to prevent a symptom of herpes simplex virus infection. Hutcherson does not teach that a composition is administered after an exposure to herpes simplex virus and within three days after the virus exposure and therefore cannot anticipate claim 1. Applicant gratefully acknowledges Examiner Sullivan's agreement in the Telephonic Interview that the amendment to claim 1 should overcome the Section 102(b) rejection of claim 1.

Claim 10 recites, in part, a method of reducing severity of a symptom of a herpes simplex virus infection in an individual infected with herpes simplex virus, comprising administering a composition comprising a polynucleotide comprising an immunostimulatory sequence (ISS) to said individual, wherein the ISS comprises the sequence 5'-purine, purine, C, G, pyrimidine, pyrimidine, C, G-3', or 5'-purine, purine, C, G, pyrimidine, pyrimidine, C, C-3'. Hutcherson does not teach administering a composition wherein the ISS comprises the sequence 5'-purine, purine, C, G, pyrimidine, pyrimidine, C, G-3', or 5'-purine, purine, C, G, pyrimidine, pyrimidine, C, C-3, and therefore cannot anticipate claim 10. Applicant gratefully acknowledges

Examiner Sullivan's agreement in the Telephonic Interview that the amendment to claim 10 should overcome the Section 102(b) rejection of claim 10.

Claim 20 recites, in part, a method of reducing recurrence of a symptom of a herpes simplex virus infection in an individual infected with herpes simplex virus, comprising administering a composition comprising a polynucleotide comprising an immunostimulatory sequence (ISS) to said individual, wherein the ISS comprises the sequence 5'-purine, purine, C, G, pyrimidine, pyrimidine, C, G-3', or 5'-purine, purine, C, G, pyrimidine, pyrimidine, C, C-3'. Hutcherson does not teach reducing recurrence of a symptom of a HSV infection in an individual infected with HSV. In addition, Hutcherson does not teach administering a composition wherein the ISS comprises the sequence 5'-purine, purine, C, G, pyrimidine, pyrimidine, C, G-3', or 5'-purine, purine, C, G, pyrimidine, pyrimidine, C, C-3, and therefore cannot anticipate claim 20.

In view of the above, Applicant respectfully requests withdrawal of the Section 102 rejection of claims.

II. Applicant acknowledges withdrawal of the rejection of claims 1-4 and 9 under Section 102(e) in view of Wagner et al. The Examiner states the following as reason for the withdrawal (See instant Office Action at page 4): "Wagner et al. does not teach that the individual treated should have been exposed to HSV."

Rejections under 35 U.S.C. § 103(a)

Claims 1-4, 9-13, 16, 19-23 and 28 are rejected as allegedly being unpatentable over Wagner et al. US PG Pub No. 2004/0030118 (previously made of record) in view of Rosenthal et al. (1997) *Clin. Infect Dis.* 24:135-139. Applicant acknowledges that the Section 103 rejection of claims 10-13, 16, 19-23 and 28 over Wagner et al. in view of Hutcherson et al. has been withdrawn.

Applicant traverses this rejection of claims. Applicant does not agree or concede that a *prima facie* case of obviousness has been established and submits that the invention is non-obvious in view of the cited references. In order to establish a *prima facie* case of obviousness, there has to

be, *inter alia*, some motivation or suggestion provided by the references, or in combination with the knowledge available to the skilled artisan, to modify the art cited or to combine reference teachings. Applicant submits that there is no motivation to combine references and, even if combined, the combination of references does not provide a reasonable expectation of successfully arriving at the claimed invention and does not teach or suggest the claimed invention.

In the instant Office Action at page 4, the Examiner withdrew the Section 103 rejection of claims over Wagner et al. in view of Hutcherson, stating: "Modifying the method of Wagner et al. to administer the therapeutic oligonucleotide to an individual during an active infection as taught by Hutcherson et al. would be inconsistent with the principle of immune system remodeling prior to antigen exposure as taught by Wagner et al."

Modifying the method of Wagner et al. (which does not teach that the individual treated should have been exposed to HSV) to administer the oligonucleotide to an individual that has been identified as seropositive for HSV (i.e. exposed at some point to HSV) as taught by Rosenthal et al. is similarly inconsistent with the principles of Wagner et al., and should be withdrawn on this point alone. Rosenthal et al. is even further removed from Hutcherson et al. as Rosenthal et al. does not disclose the use of ISS to treat HSV.

Even if Wagner et al. and Rosenthal et al. were properly combined, which Applicant does not concede, one of skill in the art would not arrive at claimed invention. Regarding claim 1, neither Wagner et al. nor Rosenthal et al, taken alone or together, teach or suggest a composition administered after an exposure to herpes simplex virus and within three days after the virus exposure in an amount sufficient to prevent a symptom of herpes simplex virus infection. Claim 10 recites a method of reducing severity of a symptom of a HSV infection in an individual *infected with* HSV. As disclosed in the specification, at page 35 lines, 10-15, in some examples wherein an individual is infected with HSV, the ISS-containing polynucleotide is administered after appearance of at least one symptom of the HSV infection. As stated by the Examiner in withdrawing the 102 rejection based on Wagner et al.: "Wagner et al. does not teach that the individual treated should have been exposed to HSV." While Rosenthal et al. identify certain HSV seropositive individuals

in their study, they have no teachings regarding administering any treatment to an individual infected with HSV, much less administering an ISS-containing polynucleotide to an individual infected with HSV. Regarding claim 20, Wagner et al. have no teachings or suggestions regarding reducing recurrence of a symptom of a HSV infection in an individual as Wagner et al. is directed to immune system remodeling *prior to* antigen exposure. Wagner et al. is non-enabling for methods for reducing recurrence of a symptom of a HSV infection in an individual infected with HSV. Rosenthal et al. have no teachings regarding any methods for reducing recurrence of a symptom of a HSV infection in an individual, much less administering an ISS-containing polynucleotide to an individual infected with HSV. One of skill in the art would not arrive at the claimed invention based upon the combination of Wagner et al. and Rosenthal et al. and the combination does not provide a reasonable expectation of successfully arriving at the claimed invention.

Applicant submits that there would be no motivation or suggestion provided by the references, or in combination with the knowledge available to the skilled artisan, to modify the art cited or to combine Wagner et al. and Rosenthal et al. reference teachings. Even if these references were properly combined, which Applicant does not concede, the combination does not teach or suggest all the limitations of the claimed invention and does not provide a reasonable expectation of successfully arriving at the claimed invention.

In view of the above, Applicant requests reconsideration and withdrawal of the rejection of claims under Section 103.

Allowable Subject Matter

Applicant gratefully acknowledges that claims 14-15 and 24-25, if rewritten in independent form and including all of the limitations of the base claim and intervening claims, would be deemed allowable.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, Applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. **377882001100**. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: December 1, 2005

Respectfully submitted,

By 
Debra J. Glaister

Registration No.: 33,888
MORRISON & FOERSTER LLP
755 Page Mill Road
Palo Alto, California 94304-1018
(650) 813-5725